DALE TECHNOLOGY

DALE400

Pacemaker Analyzer

Operating Manual

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Document Revision Record

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Introduction to the Pacemaker Analyzer Operator's Manual

This document is the operator's manual for the External Pacemaker Analyzer using V2.0 Firmware or later. This Manual contains general information about the Pacemaker Analyzer, a description of its main components, and instructions for its use. It only contains basic instructions required to service the unit. If a problem develops, the user should contact the supplier. The user should not attempt to service the unit before consulting with the supplier.

The objectives of this manual are to provide:

1. General Information about the Pacemaker Analyzer, including applications

2. Warnings, shipping and storage instructions

3. Description of the unit and specifications

4. Detailed operating instructions and descriptions of specific tests

5. User Maintenance, Service and Calibration procedures

Appendix 1. Theory of Operation of External Pacemakers

Copyright

Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Claims

Our routine method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim.

If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact Dale Technology or your local distributor.

Standard Terms and Conditions

Refunds & Credits

Please note that only serialized products (products labeled with a distinct serial number) and accessories are eligible for partial refund and/or credit. Nonserialized parts and accessory items (cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. In order to receive a partial refund/credit of a product purchase price on a serialized product, the product must not have been damaged by the customer or by the common carrier chosen by the customer to return the goods, and the product must be returned complete (meaning all manuals, cables, accessories, etc.) within 90 days of original purchase and in "as new" and resellable condition. The Return Procedure must be followed to assure prompt refund/credit.

Restocking Charges

Only products returned within 90 days from the date of original purchase are eligible for refund/credit. Products returned within 30 days of original purchase are subject to a minimum restocking fee of 15%. Products returned in excess of 30 days after purchase, but prior to 90 days, are subject to a minimum restocking fee of 20%. Additional charges for damage and/or missing parts and accessories will be applied to all returns. Products not returned within 90 days of purchase, or products which are not in "as new" and resellable condition, are not eligible for credit return and will be returned to the customer.

Return Procedure

Products sent to Dale Technology for repair must be sent via UPS or FedEx® fully insured to:

Dale Technology
Service Department
5200 Convair Drive
Carson City, NV 89706

The unit should be wrapped in at least 2 inches of Styrofoam filler or similar packing material. Unit should be accompanied by a written explanation detailing problem with the unit. For assistance please contact the Service Department at 1-800-265-7586.

Certification

This instrument was thoroughly tested and inspected and found to meet Dale Technology's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibration standards are measured against in-house performance standards using accepted test procedures.

Warranty

Warranty and Product Support

This instrument is warranted by Dale Technology against defects in materials and workmanship for one full year from the date of original purchase. During the warranty period, we will repair or, at our option, replace at no charge a product that proves to be defective, provided you return the product, shipping prepaid, to Dale Technology. This warranty does not apply if the product has been damaged by accident or misuse or as the result of service or modification by other than Dale Technology. IN NO EVENT SHALL DALE TECHNOLOGY BE LIABLE FOR CONSEQUENTIAL DAMAGES.

Only serialized products and their accessory items (those items bearing a distinct serial number tag) are covered under this one-year warranty. PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY. Items such as cables and nonserialized modules are not covered under this warranty.

This warranty gives you specific legal rights, and you may also have other rights which vary from state to state, province to province, or country to country. This warranty is limited to repairing the instrument to Dale Technology's specifications.

When you return an instrument to Dale Technology, for service, repair, or calibration, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Dale Technology will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling. All warranty claim shipments must be made on a freight prepaid basis. Also, in order to expedite your claim, please include a properly completed copy of the Service Return Form. Recalibration of instruments, which have a recommended semiannual calibration frequency, is not covered under the warranty.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industrial-approved shock-absorbent material around the instrument.

Warranty Disclaimer

Should you elect to have your instrument serviced and/or calibrated by someone other than Dale Technology, please be advised that the original warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization. We strongly recommend, therefore, that you send your instrument to Dale Technology for factory service and calibration, especially during the original warranty period.

In all cases, breaking the tamper-resistant Quality Seal should be avoided at all cost, as this seal is the key to your original instrument warranty. In the event that the seal must be broken to gain internal access to the instrument (e.g., in the case of a customer-installed firmware upgrade), you must first contact Dale Technology's technical support department at 800-265-7586. You will be required to provide us with the serial number for your instrument as well as a valid reason for breaking the Quality Seal. You should break this seal only after you have received factory authorization. Do not break the Quality Seal before you have contacted us! Following these steps will help ensure that you will retain the original warranty on your instrument without interruption.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Dale Technology will not be responsible for any injuries sustained due to unauthorized equipment modifications.

TABLE OF CONTENTS

1. GENERAL INFORMATION

1.1 Warnings

1. **Under no circumstances should the unit be used on a Pacemaker which is CONNECTED TO A PATIENT.**

2. Remove Batteries if the instrument is to be stored for a long period of time.

3. If using with a mains adaptor, make sure the delivered supply is 6-9volts. Incorrect voltages or polarity (see back overlay) may cause permanent damage to the unit.

1.2 General Information

The Pacemaker Analyzer is designed as a universal analyzer/tester suitable for most types of external pacemaker. The current version of the software (ROM program) enables the tests listed below to be performed on invasive and non-invasive types of external pacemaker.

The test procedures available are as follows:

* Pulse Width (ms)
  Pulse Amplitude (V) and (mA)
  (mA only for transthoracic types)
  Pulse Interval (bpm)

* A-V time interval (ms) provides a measurement of the time between atrial and ventricular pulses from dual chamber pacemakers.

* Demand mode - R, S and T wave sensitivity tests using pulse widths of 5, 10, 15, 17, 20, 40, 50, 100 & 200ms and amplitudes of 0-25mV. (30ms width also with firmware version 2.6 or later) All these settings are available with Sine Squared (SSQ) (Haversine), Triangular (TRI) and Square wave (SQU) pulses. An alternative 'ISO' waveform is also available but only as a positive wave with a width of 15ms.

* TAKEOVER and INHIBIT rate can be measured on demand pacemakers. On some pacemakers these may be the same value, but on others a RATE HYSTERESIS is introduced to prevent frequent changes of mode.

* Response to 50/60Hz a.c. interference. The Pacemaker Analyzer provides a 50Hz or 60Hz sinusoidal signal with amplitudes from 0-25mV, to establish the level of interference causing malfunction. At the same time a simulated R-wave can be introduced for pacemakers operating in demand mode.

* Pulsed Refractory Period (ms) measures the time after a paced pulse during which the pacemaker will not respond to a received stimulus.

* Sensed Refractory Period (ms) measures the time after a sensed stimulus during which the pacemaker will not respond to a further stimulus.

* Extended Test. This is a long term test which averages the pulse amplitudes and pulse intervals of the first ten pulses received, and reports if any subsequent pulses (amplitudes or intervals) are not within 10% of the average values.

All results may be printed using the parallel port or sent to a computer via the serial port. The Pacemaker Analyzer can also be controlled from a computer.

1.3 Applications of Pacemaker Analyzer

The Pacemaker Analyzer has been designed for use in the following applications.

1. Routine checking of pacemakers in the cardiology department using three or four of the basic tests above in only one or two combinations of pacemaker/analyzer settings. Such tests might be performed before a new patient is connected to the pacemaker.

2. Checking in the Biomedical Engineering Department after service or repair. For routine maintenance a basic set of tests may be performed to demonstrate the continued satisfactory function of pacemakers. Alternatively, for acceptance testing, evaluations and after repair a fuller set of tests can be performed and the results recorded (printed) as a QA baseline.

3. As an aid to troubleshooting and repair. Faults on pacemakers can be identified using the Pacemaker Analyzer. Intermittent faults can be located using the Extended test, which will identify even occasional variations from the set pacing parameters.

4. For use in teaching and demonstrating the functioning of pacemakers. As well as measuring the pulse parameters of pacemakers the Pacemaker Analyzer is a powerful simulator, which can be used to generate signals required when demonstrating the INHIBIT and TAKEOVER rates, the R, S and T wave SENSITIVITY, and the REFRACTORY PERIOD measurements.

1.4 Power Supply and Batteries

The unit may be powered from batteries (4 x 1.5 volt AA cells) or from a 6-9 volt external supply (US version). When used on an external supply the cells are automatically disconnected. The cells are not charged from the external

supply. We recommend the use of leak-proof Alkaline cells which have a long shelf and service life. A battery-low warning appears on the display when the voltage has fallen sufficiently to need replacing. Rechargeable cells (1.2v) and Mercury cells (1.35V) should be avoided because of the lower output voltage. We recommend the use of an external supply whenever possible and particularly when performing the extended test, to conserve battery power.

1.5 Connecting to a Printer

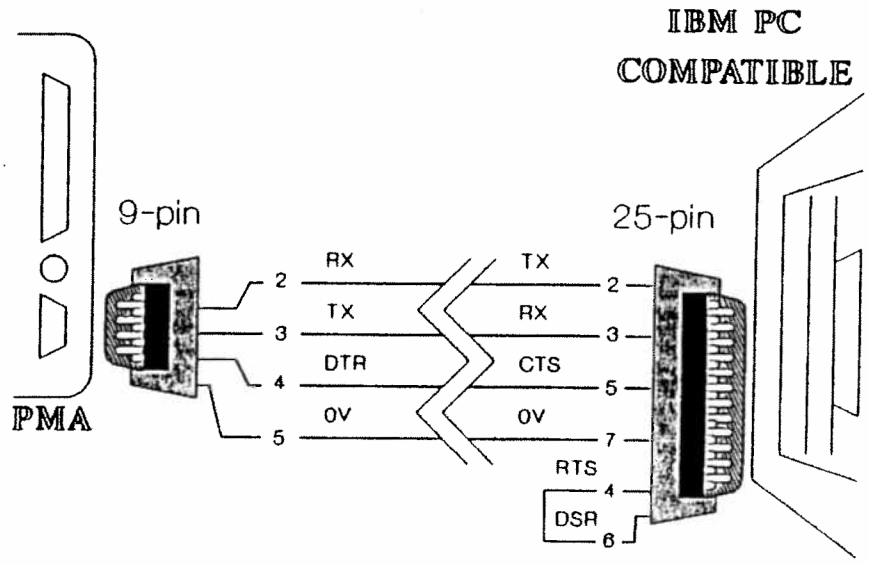
The printer port is the 25-way D-type connector on the top of the instrument. This provides a standard Parallel printer signal with the same pin configuration as used on IBM compatible computers. The standard printer lead used with these computers should work with the Pacemaker Analyzer.

Information is sent to the printer when the [PRINT] button is pressed. Usually this prints the contents of the LCD Display. In the EXTended test, the printer is particularly useful as any pulses from the pacemaker which are not within the set limit (+/-10%) of the average are sent to the printer.

Only standard ASCII codes are used and thus the interface should work with almost all basic printers.

1.6 Using the Computer Interface

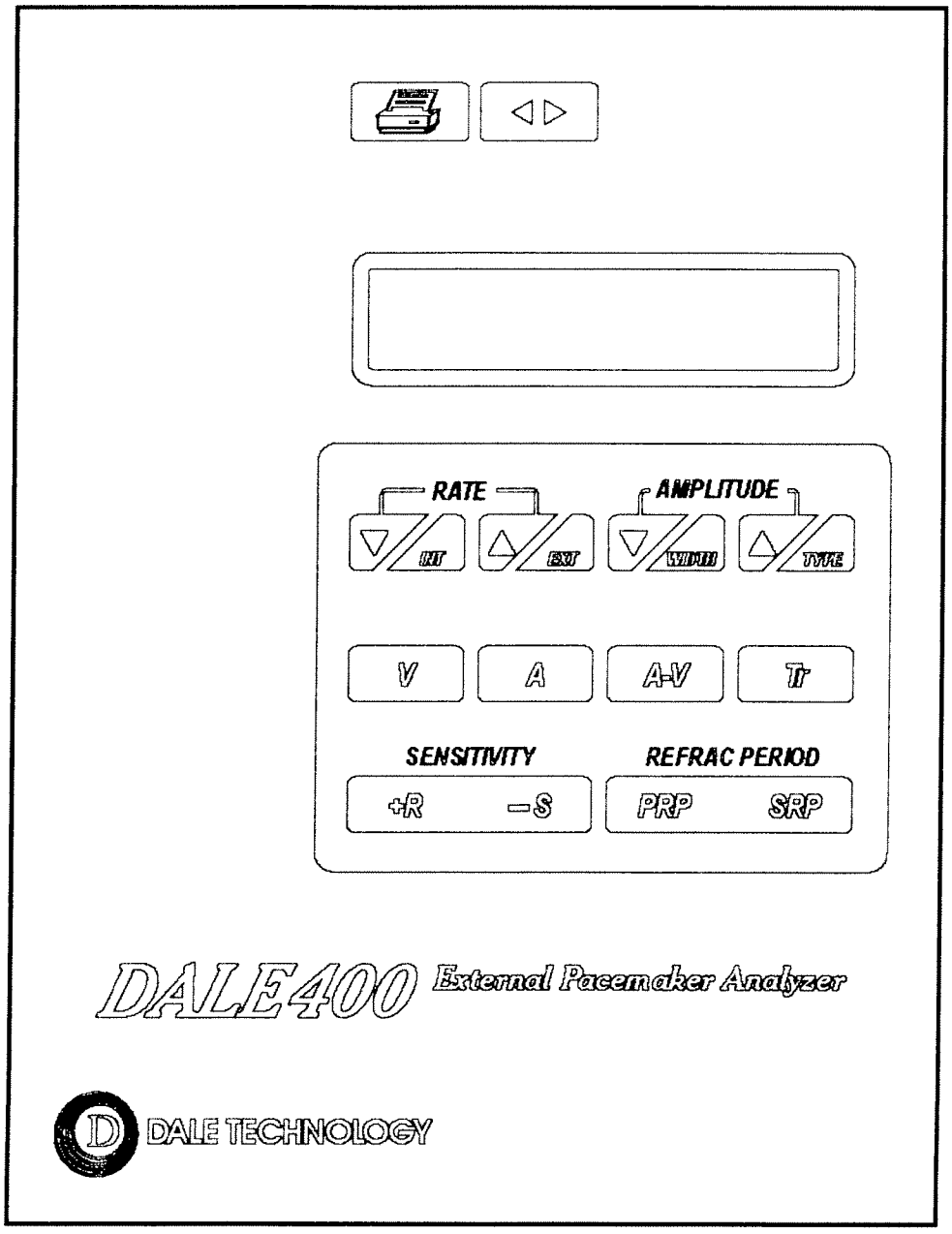
A serial computer communication port is provided via 9-pin Female D-type connector on the top face of the instrument. This is intended to send test results direct to a computer for paperless storage of test results, and for use under computer control. The protocol (bi-directional) is 9600 N 8 1.



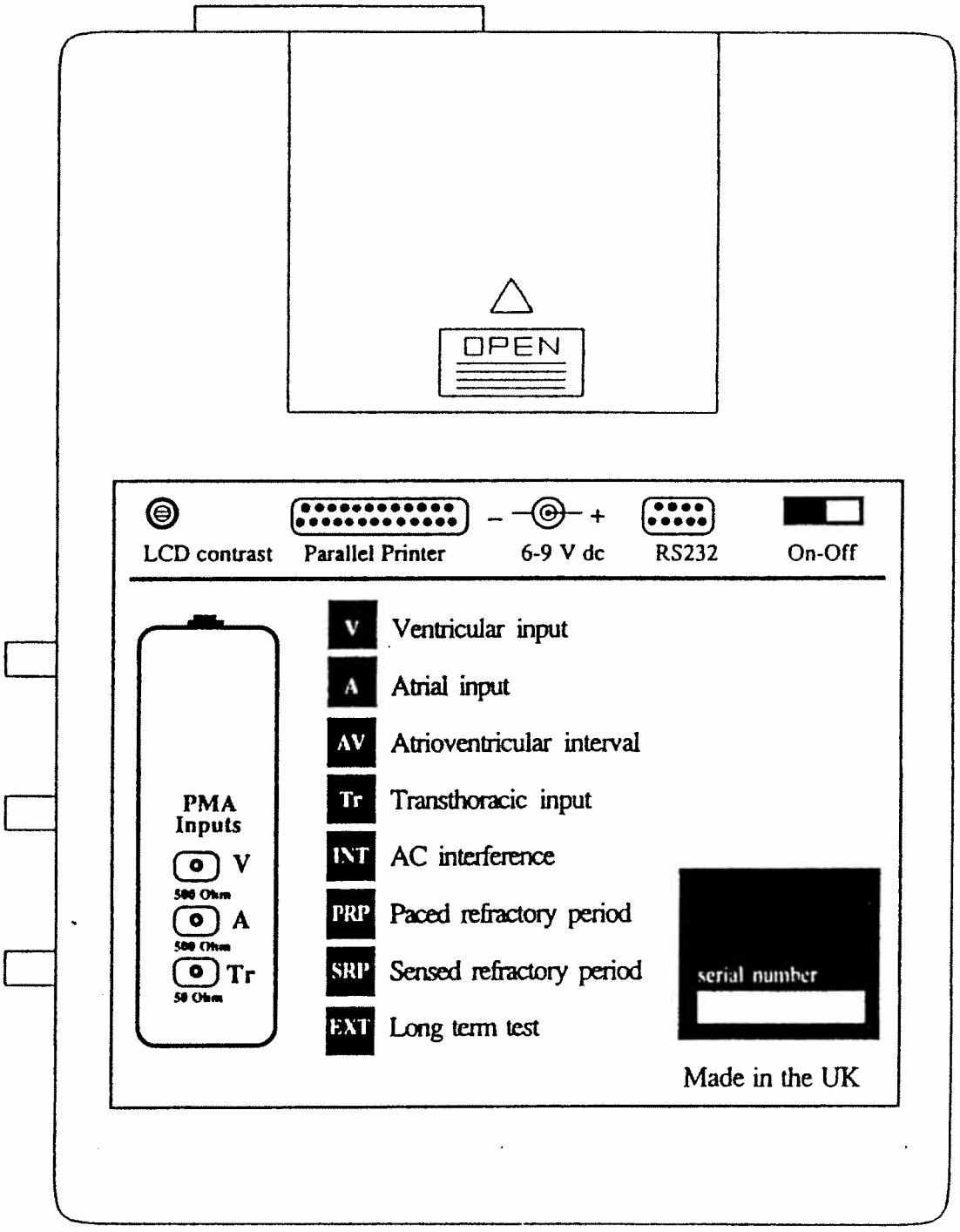
RS232 connections Pin 2=RX receive, Pin 3=TX Transmit, Pin4=DTR, Pin5=GND.

2. DESCRIPTION AND SPECIFICATIONS

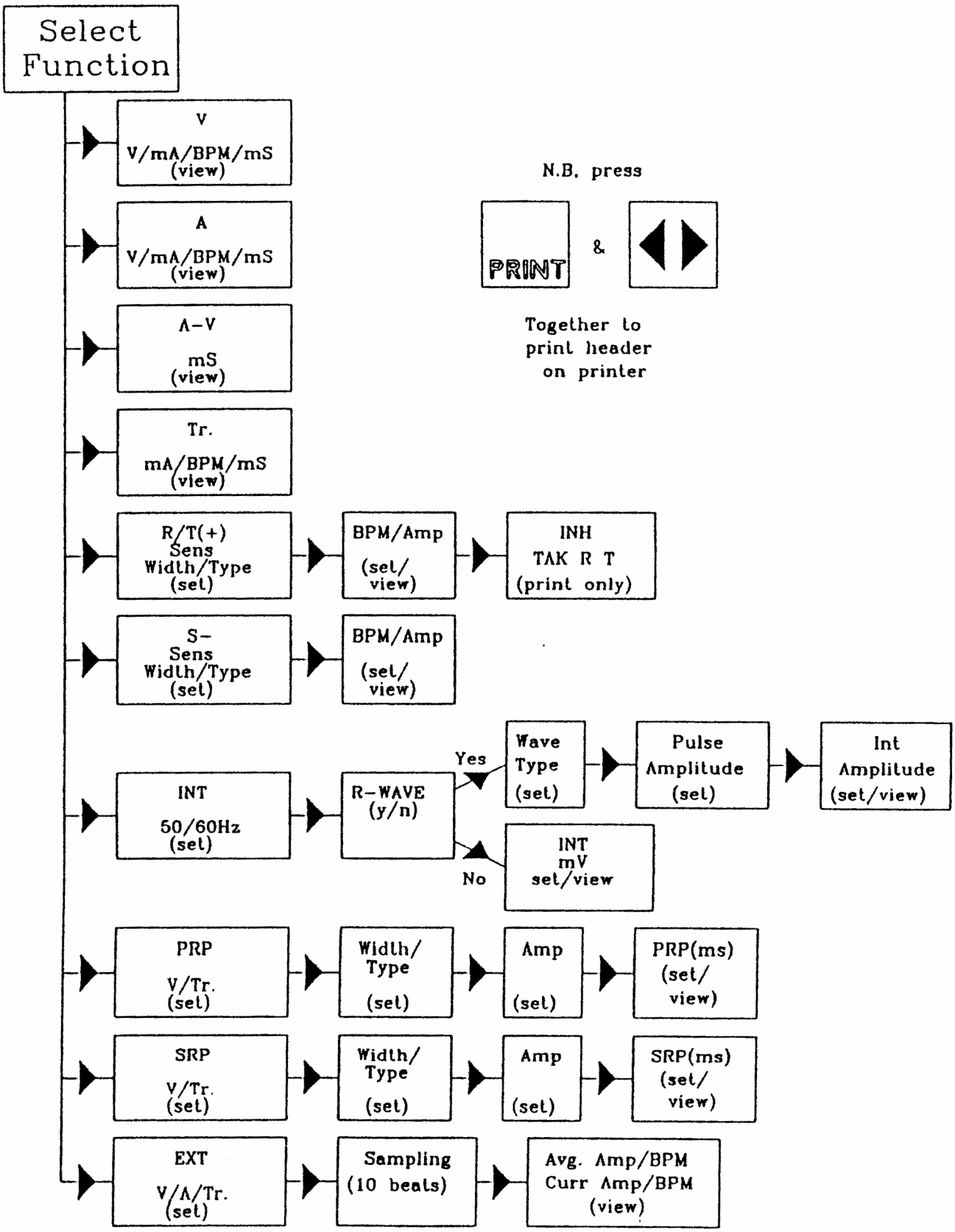
2.1 Front View



2.2 Rear View


OPEN
LCD contrast
Parallel Printer
6-9 V dc
RS232
On-Off
PMA Inputs
V
500 Ohm
A
500 Ohm
Tr
50 Ohm
V Ventricular input
A Atrial input
AV Atrioventricular interval
Tr Transthoracic input
INT AC interference
PRP Paced refractory period
SRP Sensed refractory period
EXT Long term test
serial number
Made in the UK

2.3 Program Menu



2.4 Input Details

Ventricular Pacing Signal/Atrial Pacing Signal
Connectors: Sub-miniature Bayonet (SMB) male
Leads - 50cm coaxial with female SMB - to 4/2mm pins
(0.3-12.5V/25mA, 500 ohm load, 30-1200 BPM)

Transthoracic Pacing Signal
Connector: Sub-miniature Bayonet (SMB) male
(10-250mA, 50 ohm load, 30-1200 BPM)

2.5 Output Details

Parallel Printer Port
25-way D type female connector

Serial Computer Port
9-Pin Female D-type connector
9600 Baud, 8 bits, no parity, 1 stop
Bi-directional

2.6 Display

2 line by 16 character LCD

2.7 Power Requirements

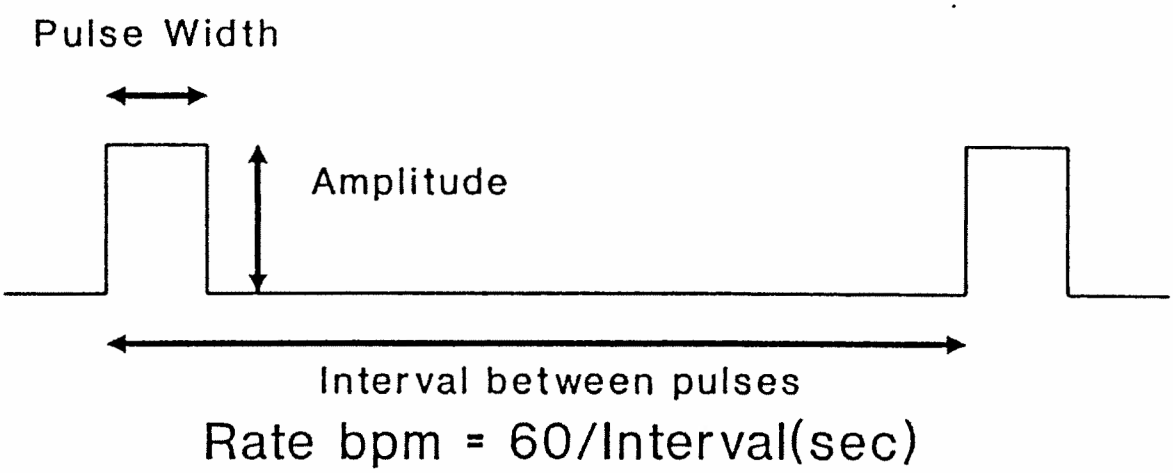
Batteries: 4x 1.5 volt AA cells (rechargeable types not suitable)
- current drawn 30mA approx.
- 'Battery Low' message appears when voltage falls below 5.5. Readings become inaccurate when this message shows.

External Supply 6-9V
- connecting external supply automatically disconnects the battery.

2.8 Size/Weight

Case 135 x 191 x 46mm plus protruding connectors
Weight 600g (approx)

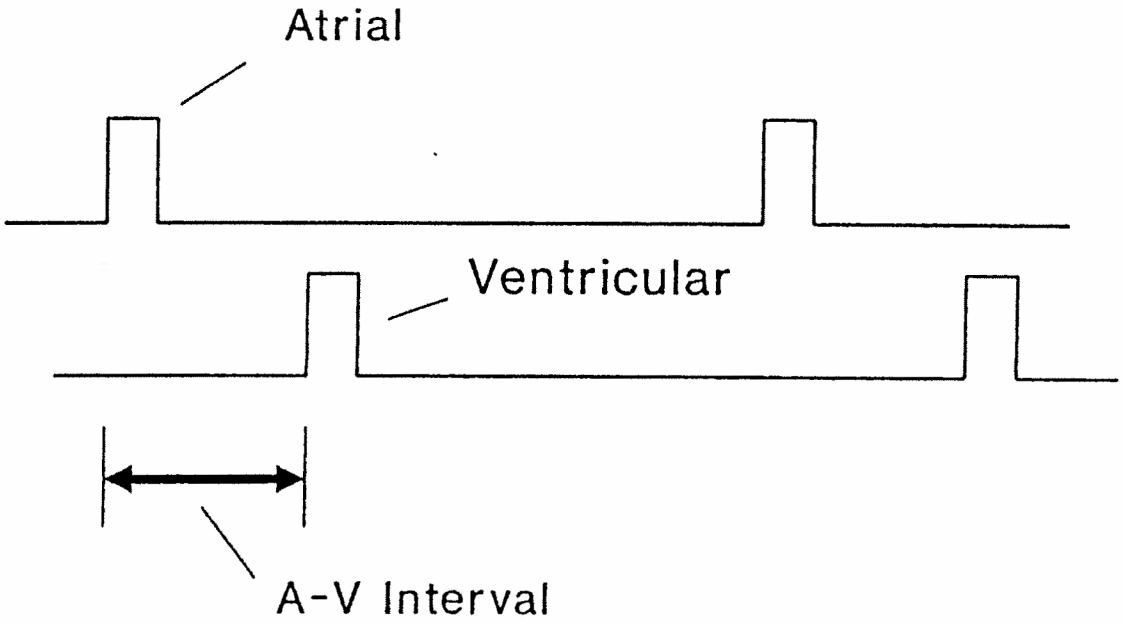
2.9 Measurement of Pacing Pulse



-Amplitude
-(0.3-12.5V/25mA) invasive
Measurement taken 0.1ms after start of pulse
-(10 - 250mA) non-invasive
Measurement taken 2ms after start of pulse
-Rate 30-1200 bpm
-Pulse length 0.5 (2.2 for transthoracic) - 50mS in 0.01mS steps

2.10 A-V Pulse Time Interval

-(0-1000ms)



2.11 50/60Hz Interference Signal

Delivered via the V signal port.

1. 0 - 50mV ac peak to peak at 50hz or 60Hz:

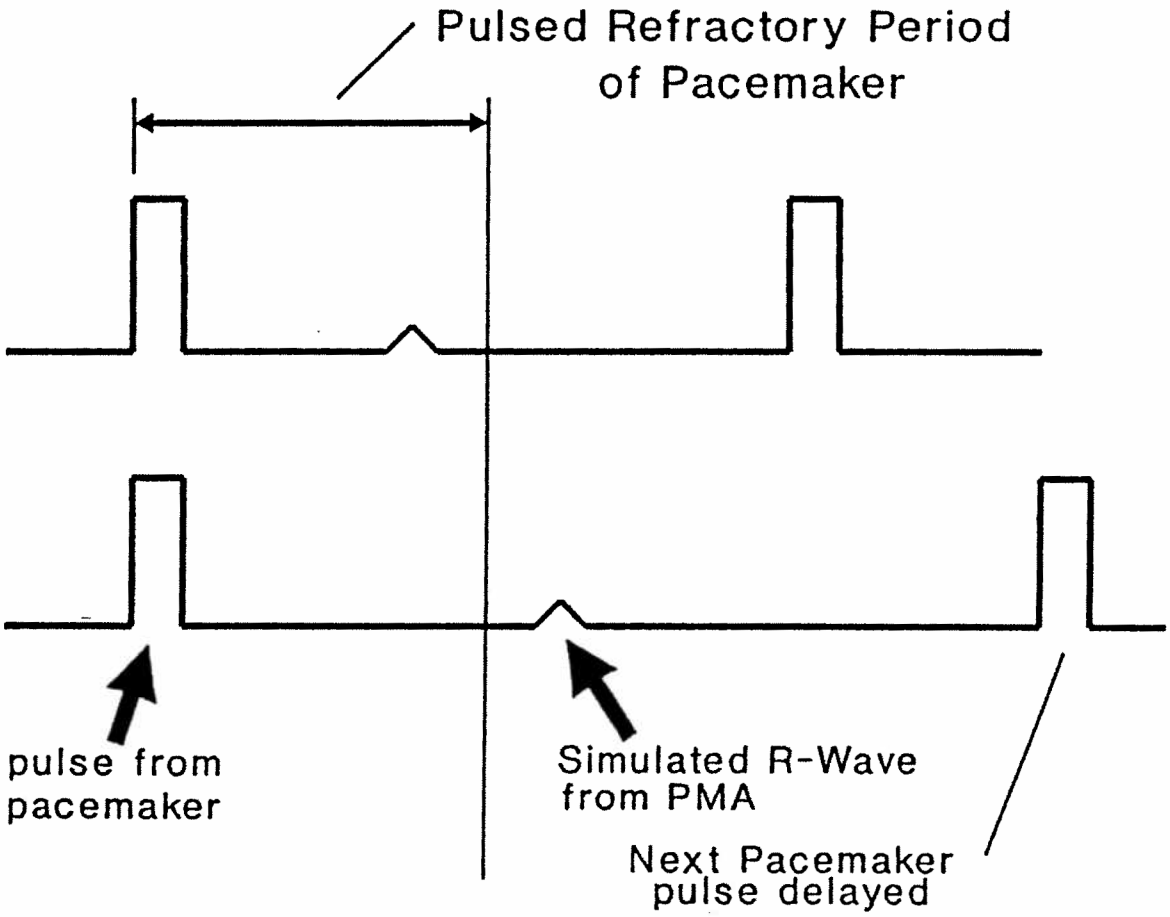
   - in 1.0mV steps above 3mV
   - in 0.2mV steps below 3mV

2. 0 - 50mV ac peak to peak at 50Hz or 60Hz, together with simulated R-wave of 20ms width at 120BPM, 0-25mV, with choice of SSQ (Sine Squared), TRI (triangular) or SQU (square) waves.

2.12 Refractory Period Measurements

Pulsed Refractory Period

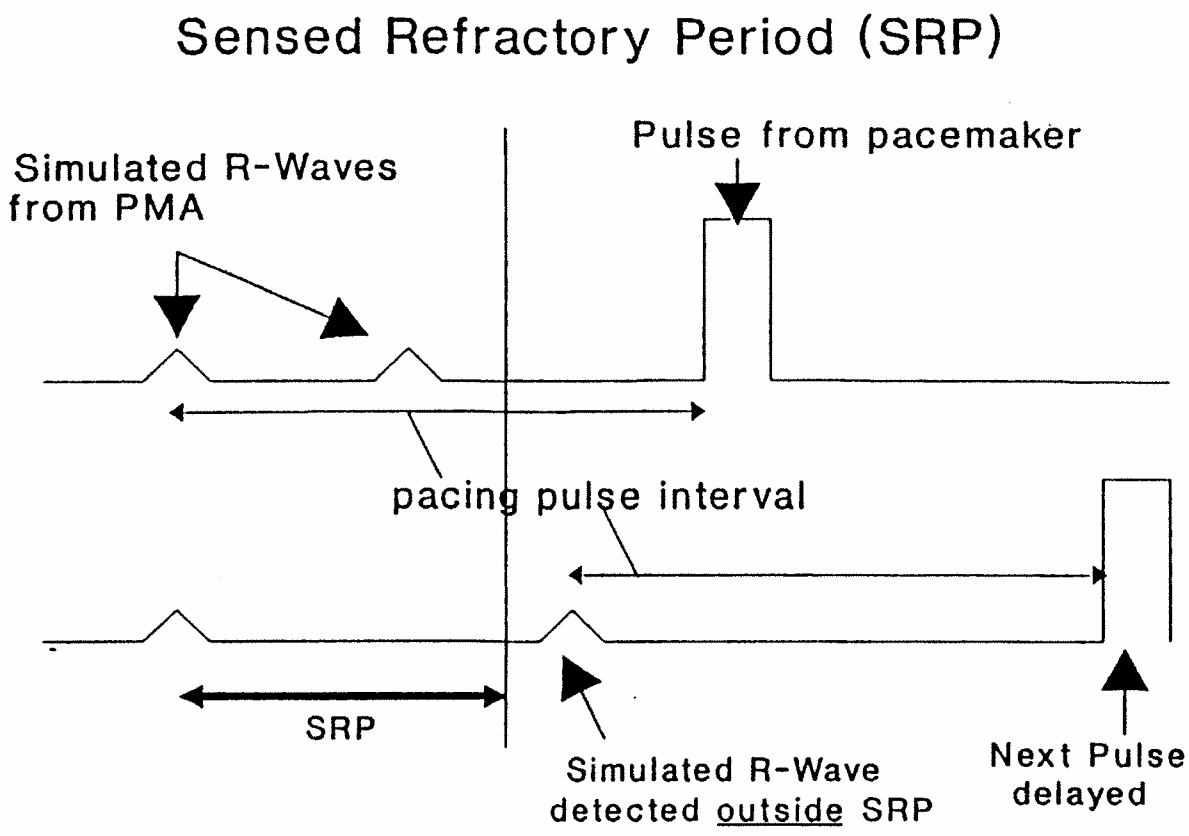
This is the time after delivery of a pacing pulse during which the pacemaker will not detect cardiac activity (R-wave) (30 - 500ms)

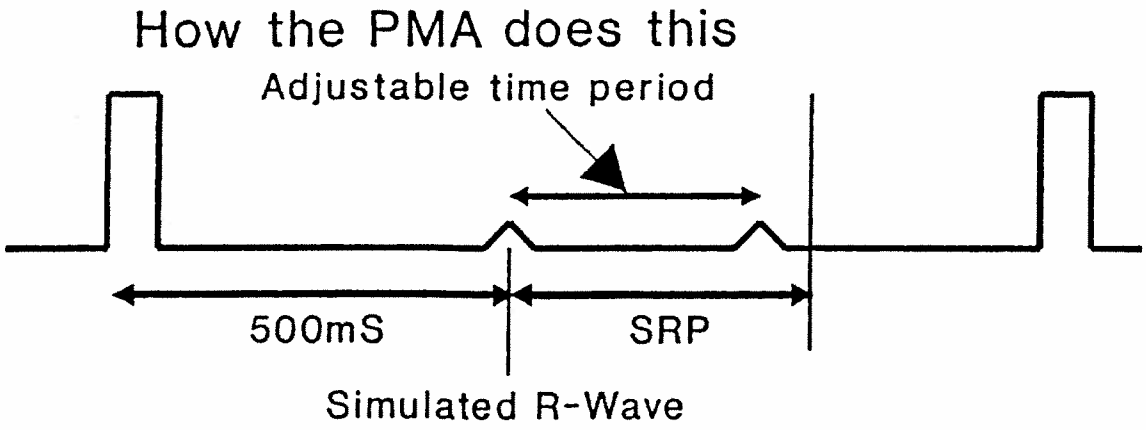


Note: The time of the simulated R-wave is assumed to be the midpoint of the wave.

2.13 Sensed Refractory Period

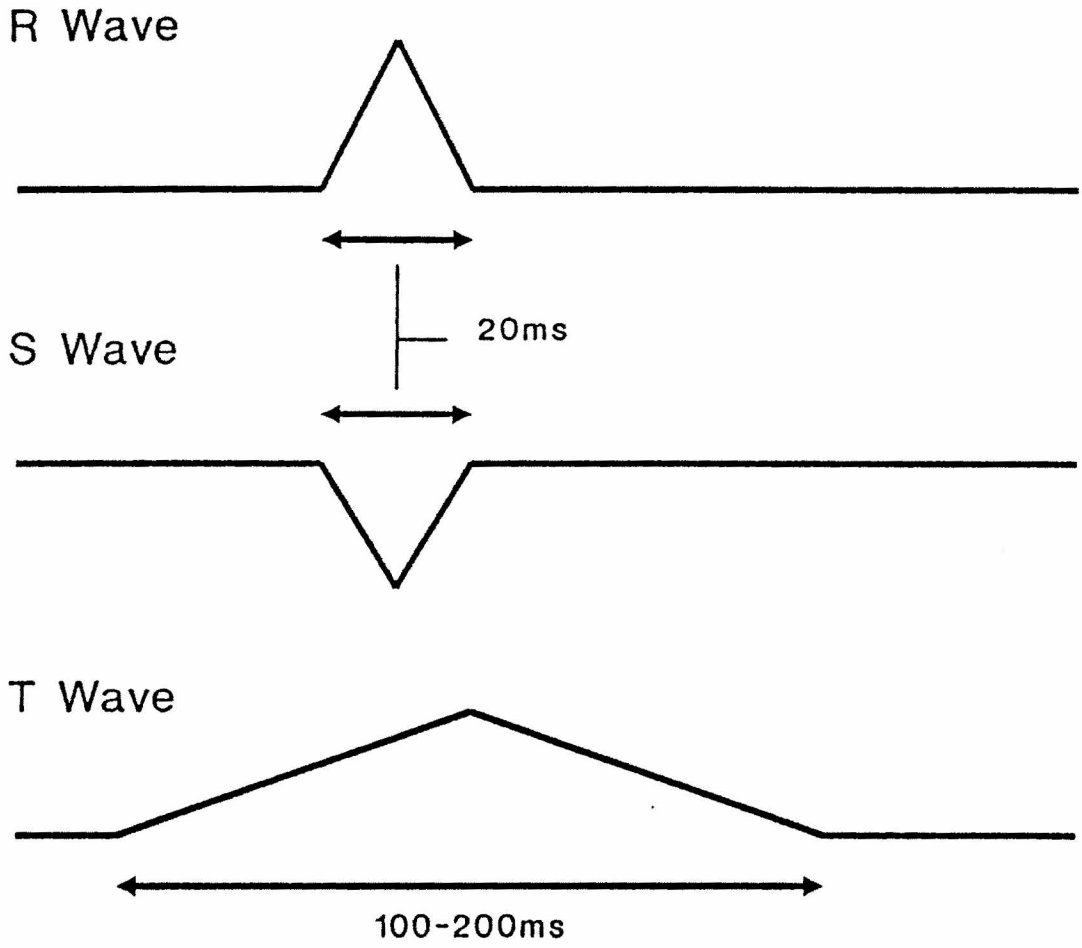
This is the period after the pacemaker senses cardiac activity (simulated R-wave) during which it will not detect a further R-wave.
(30-500ms)





2.14 Simulated R, S & T waves

Examples of R, S and T waves.

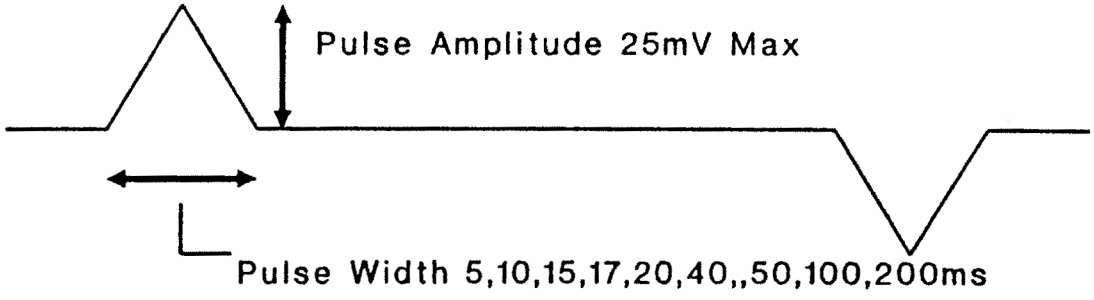


Width Settings	5, 10, 15, 17, 20, 40, 50, 100, 200ms (& 30ms with ver. 2.6 or later)
Rate Settings	30-125 bpm
Amplitude Settings	+/-0 to 25mV: in 0.1mV steps for R, S, T Sensitivity in 1.0mV steps for PRP, SRP, and INT
Waveform Selection:	Square (SQU) Triangular (TRI) Sine Squared (SSQ) (Haversine) ISO Waveform

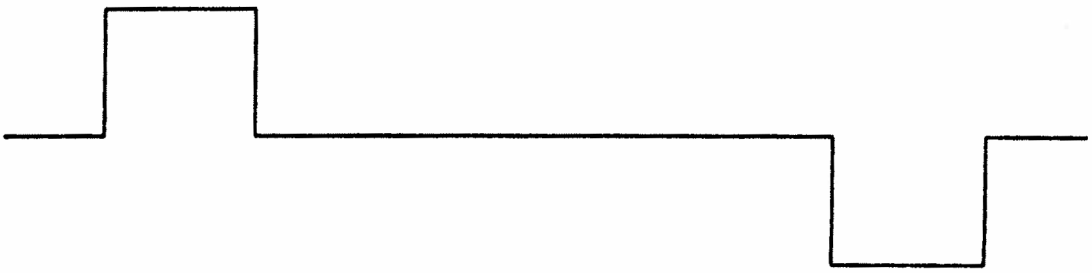
2.15 Waveform Options

Sine Squared Waveform (Haversine)

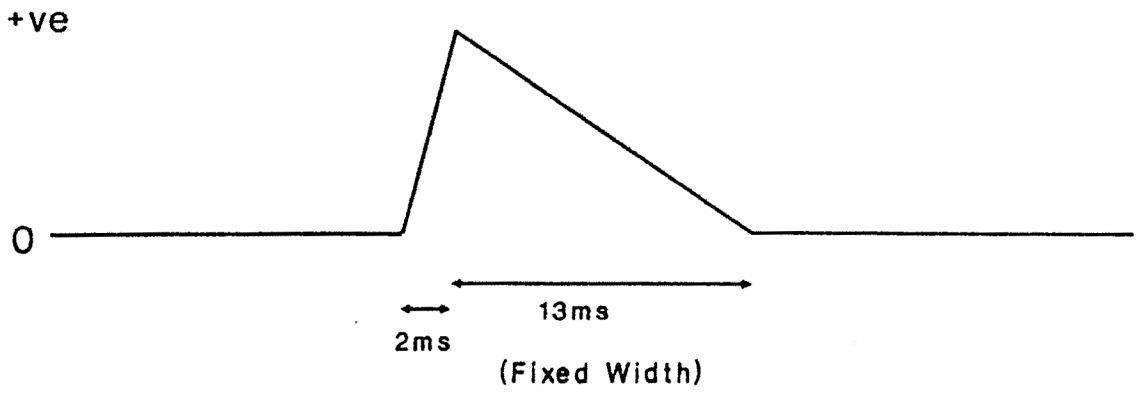
Triangular Waveform



Square Waveform



'ISO'



2.16 Long Term Tests

A reference value for the pulse rate and amplitude is established from the first 10 pulses. Thereafter any deviation over 10% is flagged and sent to the printer.

2.17 Overall Accuracy Statements

All timings	Clock:1% +/- 1 digit Note: Pulse length timing measurement requires detection of start and end times, which in turn depends upon pulse amplitudes and rise/fall times.
All amplitudes	5% +/- 1 digit Note: Amplitude measurements are an average value taken over approximately 80 microseconds. Very short pulses with rapid rise/fall times may be subject to apparent error due to this averaging time.

3. OPERATING INSTRUCTIONS

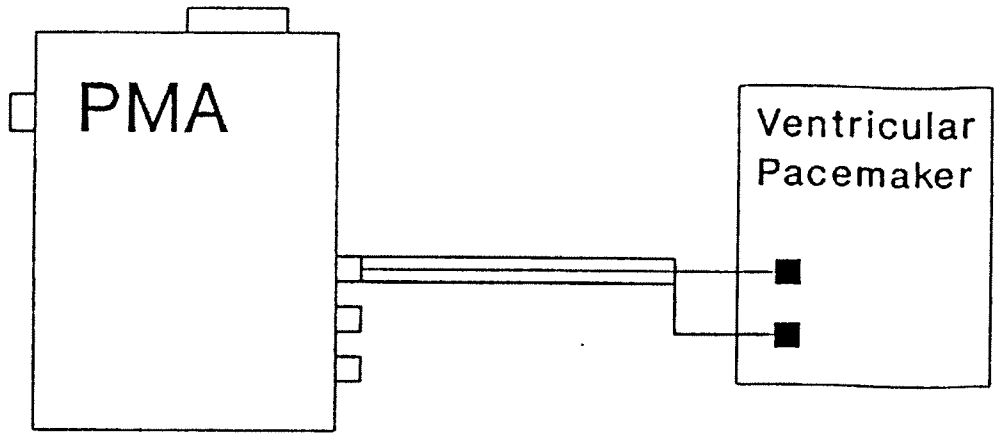
3.1 Overview of Test Procedures

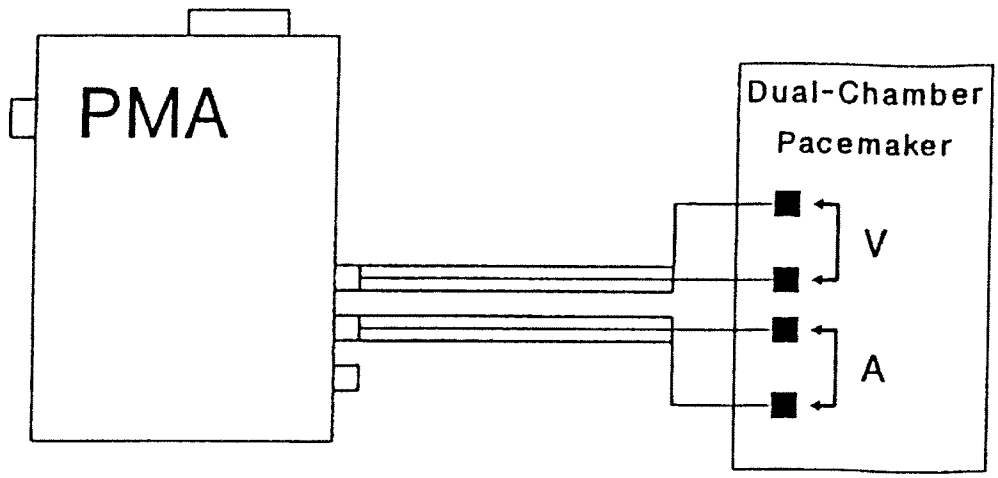
The test procedures set out below are to meet two different requirements:

1. A short test covering the more basic functions of the pacemaker at fixed control settings.

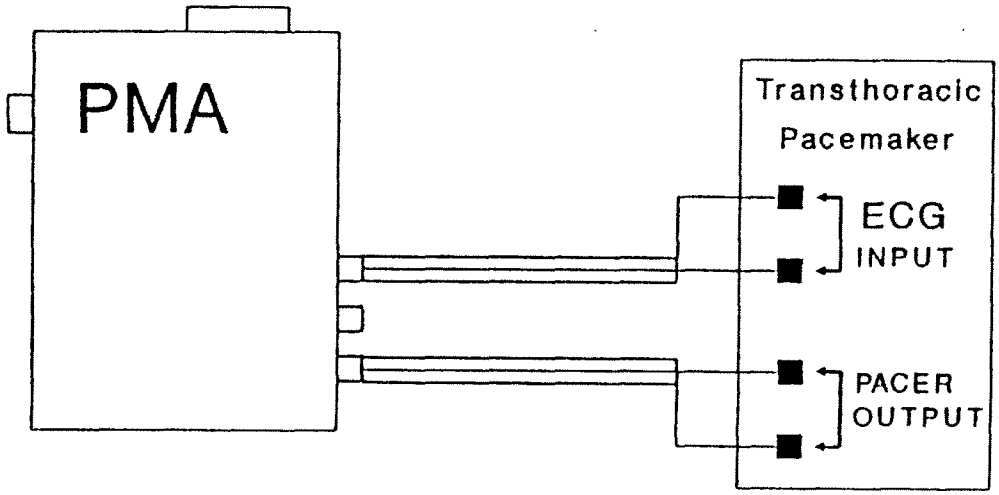
2. The full tests which might need carrying out during a full analysis of pacemaker function. The full test would include the supplementary tests below and the operations set in italics in the Short Test below.

3.2 Connection to the Pacemaker:-Invasive types

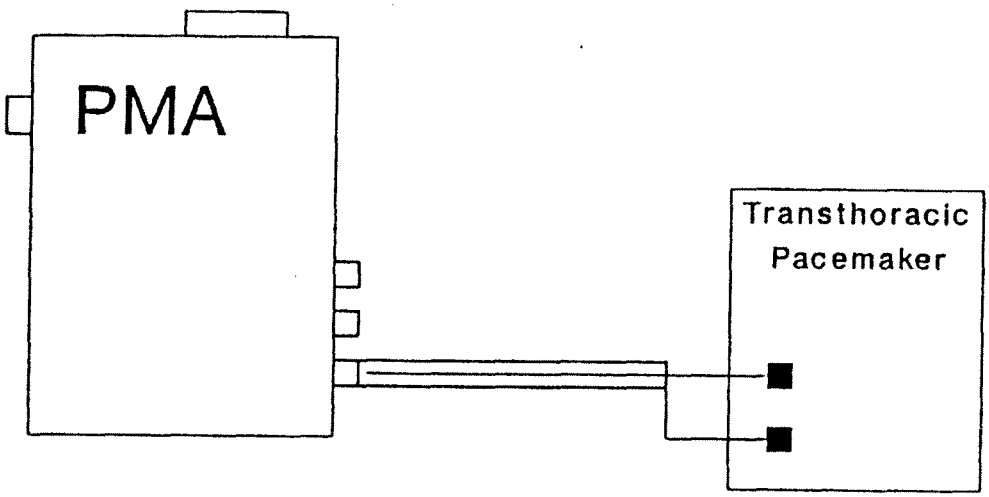




3.3 Connection to the Pacemaker:-Transthoracic types



Demand Test



(Non-demand test)

3.4 Short Test Procedure

This is a proposed procedure for the quick testing of pacemakers before reuse or as a basic QA test.
The comments set in italics suggest expansion of the test to include other pacemaker settings for a fuller test.

* Connect the pacemaker appropriately.

* Connect a printer/computer if required.

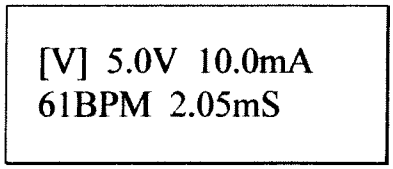
* Use the mains supply adaptor if many tests, and/or long term tests are to be conducted.

* Press [>>] followed by [PRINT] to produce a test header on the printer.

* Set Pacemaker to 60bpm, 5v (10mA), 2ms pulse length.

3.5 Ventricular Pulse Test

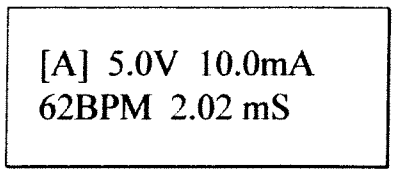
* If testing Ventricular Pacemaker press [V]
If testing Transthoracic Pacemaker press [Tr]
This will measure the pacing pulse for amplitude, pulse width, and pulse rate e.g.



Press [PRINT] if printed/computer output is required.
Press [>>] after completion of the test.

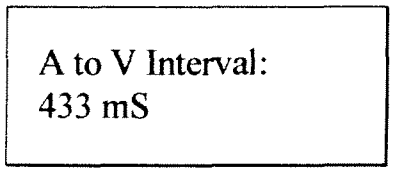
3.6 Atrial Pulse Test

* If testing a dual chamber Pacemaker press [A]. This will measure the Atrial pacing pulse.



Press [PRINT] if print is required.
Press [>>] to return to the menu.

Press [A-V] to measure the A-V time interval:

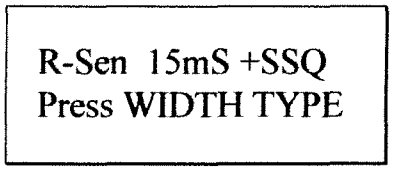


Press [PRINT] or [>>] to continue.

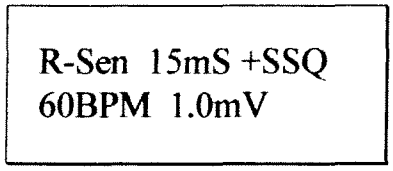
The above tests have used 'typical' pacemaker settings. The tests may now be repeated to test the pacemaker outputs at high and low rate setting of amplitude, pulse width, pulse rate and A-V interval (if applicable)

3.7 R Wave Sensitivity, Inhibit and Takeover Rate

If the pacemaker has a sensitivity control, set this to 2mV. Set the pulse rate to 60bpm. The Pacemaker should now be in the 'demand' mode. Press [R]



This causes the default value of SINE SQUARED (SSQ) Pulse and 15ms duration to be generated. These can be changed using the Pulse [WIDTH] and [TYPE] keys and the settings accepted by pressing [>>]. The display will now show:



Now set the Pacemaker Analyzer output rate to 70bpm using the [RATE] up-down buttons. Starting at the default value of 1mV increase the Pacemaker Analyzer pulse amplitude using the [Amplitude] up-down buttons until the Pacemaker stops pacing. **This value is the R-wave Sensitivity.**

If the result is to be printed then press [PRINT]. This causes a MENU to be shown to select the title for the printed output. This is because a number of tests include the same parameters.

The correct TITLE for the printed results is selected by pressing the key under the relevant prompt as follows:

INH	Inhibit Rate
TAK	Takeover Rate
R	R-Wave Sensitivity
T	T-Wave Sensitivity

Note that T-wave sensitivity differs from R-wave only in that the simulated wave is much longer (e.g. 150mS instead of 15mS).

* Takeover Rate. Find the R-Wave Sensitivity as above. Increase the amplitude by another 5mV and the decrease the Pacemaker Analyzer output rate until the Pacemaker delivers pulses again. This value is the Takeover Rate.

  Select title for printing as above.

* Inhibit Rate. Find the Takeover Rate as above. Continue to decrease the Pacemaker Analyzer rate so that the Pacemaker is beating consistently. Now increase the rate until the Pacemaker output is inhibited again. This is the INHIBIT rate.

  Note: The difference between the Takeover Rate and the Inhibit Rate is the Rate Hysteresis. On some pacemakers the two rates are the same, but on others a deliberate Rate Hysteresis in introduced to prevent frequent change of mode.

  Select title for printing as above.

3.8 Sample Results

Printed/Computer Results for a dual chamber pacemaker, following the above short test procedure might be as the following example.

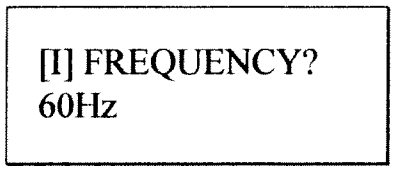
```
          * PACEMAKER ANALYZER *    V2.9

Serial No    : A123
Model No     : X 1448
Manufacturer : PM. INC.
Location     : CARDIAC DEPT
Hospital No  : RX 236 Y
Technician   : H. WORTHING
Date         : 18 / JAN / 2003
Comment      INTERPATIENT TEST
Comment      ------------------------
Comment      ------------------------


VENTRICULAR OUTPUT
amplitude.......      5.0V      5.0mA
pulse width.....    2.10mS
rate............     60BPM

ATRIAL OUTPUT
amplitude.......      4.8V      4.8mA
pulse width.....    2.10mS
rate............     61BPM

A to V INTERVAL     451mS

R-SENSITIVITY
     2.2mV    [   70BPM       15mS    +SSQ]

TAKE-OVER RATE
     63BPM    [   5.0mV       15mS    +SSQ]

INHIBIT RATE
     65BPM    [   4.5mV       15mS    +SSQ]
```

3.9 Supplementary Tests

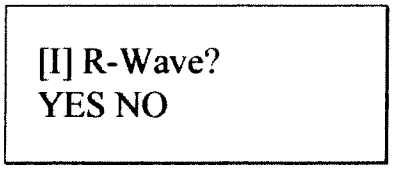
3.10 Response to AC Interference.

Set the pacemaker to demand mode at 60BPM and 2mV sensitivity.

Press [INT]

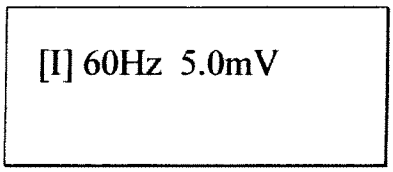


Select frequency using [RATE] controls and accept by pressing [>>]



Manufacturers of some pacemakers recommend a test of susceptibility to a.c. interference in the presence of simulated R-wave. If this test is required select YES by pressing the key under the word. If only mains supply interference is needed select NO.

If No R-Wave has been selected then the following screen shows:
[I]60Hz 5.0mV

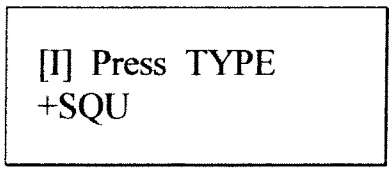


The PMA is now delivering a 5mV 50/60Hz sinusoidal signal.

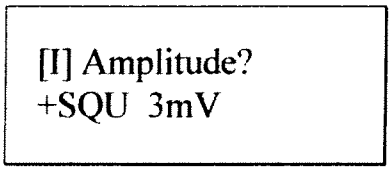
The amplitude of the interference signal may be adjusted with the AMPLITUDE controls. Increase the amplitude until the pacemaker responds either by indication that mains interference has been detected or by reverting to fixed rate synchronous pacing. The interference signal can be raised to 50mV. Some pacemakers will not be affected by this.

Press [PRINT] or [>>] to end the test.

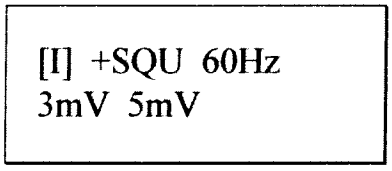
If R-Wave has been selected the display becomes:



Select the required PULSE waveform (SSQ, SQU, TRI) using the [TYPE] button (SQU is the default), and press [>>] to accept.



Select the required PULSE amplitude using the [Amplitude Buttons] (3mV is the default), and press [>>] to accept.



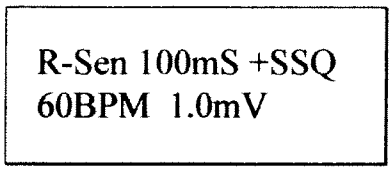
The Pacemaker Analyzer is now delivering a simulated R-wave at 120 BPM (fixed), with SQU waveform at 3mV (previously set), and 60Hz sinusoidal interference at 5mV peak to peak amplitude. The interference signal can now be changed using the [Amplitude] controls.

Increase the interference signal until the pacemaker performance is affected.

Press [PRINT] or [>>] to end the test.

3.11 T-wave sensitivity

Repeat the R-wave sensitivity test (see above) using a +ve, SSQ simulated T-wave of 100 or 200ms duration.

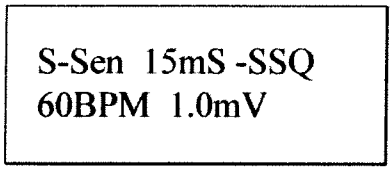


When printing the results, remember to select [T] for the correct print header.

The pacemaker should be less sensitive to T-waves than it is to either R or S-waves.

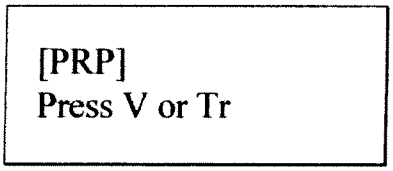
3.12 S-wave sensitivity

Press [S]. Repeat the sensitivity test but use the default -ve, SSQ, S-wave of 15ms duration.

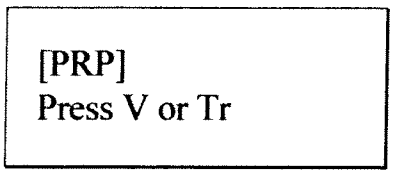


3.13 Pulsed Refractory Period.

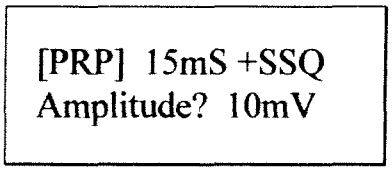
With the pacemaker set in demand mode at 60BPM press [PRP].



Select [V] or [Tr]

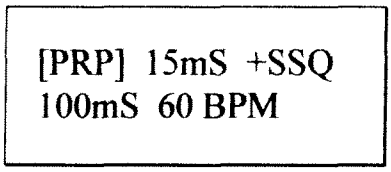


Set pulse [WIDTH] and [TYPE] and accept [>>]



The default pulse amplitude is 10mV. This value is chosen to be above the sensitivity setting of most pacemakers, i.e. the Pacemaker Analyzer pulse has a high enough amplitude to be detected by the pacemaker. The setting may be adjusted in steps of 1mV using AMPLITUDE controls.

Press [>>] to accept these values.



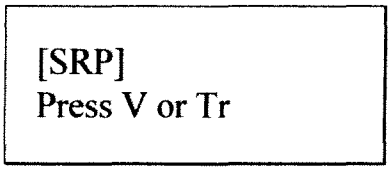
The Pacemaker Analyzer will now detect pacemaker pulses and will deliver simulated R-Wave signals 100ms after the received pacemaker pulse. The pacemaker pulse rate is shown on the Pacemaker Analyzer display. 100ms delay is within the refractory period of many pacemakers in which case the rate shown should be that set on the pacemaker (60bpm).

Change the delay using [Rate] to find the point at which pacemaker rate starts to fall. At this point the simulated R-wave from the Pacemaker Analyzer has been received by the pacemaker and is causing the pacemaker rate to respond accordingly.

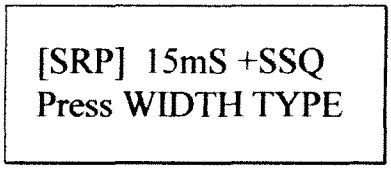
Press [PRINT] or [>>] to end the test.

3.14 Sensed Refractory Period.

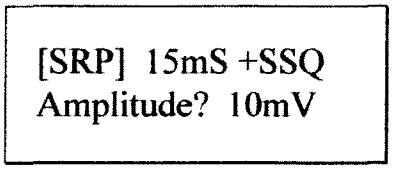
With the pacemaker set in demand mode at 60BPM press [SRP].



Select [V] or [Tr]

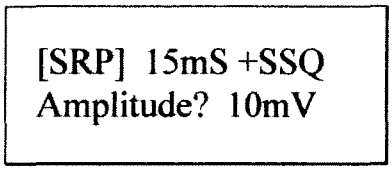


Set pulse [WIDTH] and [TYPE] and accept [>>]



The default pulse amplitude is 10mV. This value is chosen to be above the sensitivity setting of most pacemakers, i.e. the Pacemaker Analyzer pulse has a high enough amplitude to be detected by the pacemaker. The setting may be adjusted in steps of 1mV using AMPLITUDE controls.

Press [>>] to accept these values.



The Pacemaker Analyzer will now detect pacemaker pulses, wait 500ms after each detected pulse (to ensure refractory period is exceeded), deliver a simulated R-wave, wait 100ms and deliver a second simulated R-wave.

If the second simulated R-wave is within the sensed refractory period of the first it should not be detected by the pacemaker.

Thus the display should now show that the pacemaker is pacing at 40BPM. This is because of the 500ms delay before the first simulated R-wave which causes a consequent reduction in the pacemaker rate.

Change the delay after which the second simulated R-wave is delivered using the [RATE] control to find the point at which the pacemaker rate falls. This will occur when the second simulated R-wave falls outside the SENSED REFRACTORY PERIOD of the pacemaker.

Press [PRINT] or [>>] to end the test.

3.15 Long Term Test (EXTended Test)

Set the pacemaker to non-demand mode and the desired output conditions (amplitude, rate and pulse width) e.g. 5V, 60BPM, 2ms, and Press [EXT]

Extended Test: V, A or Tr?

Select input to be used [V],[A], or [Tr].

The Pacemaker Analyzer will now sample the first 10 pulses received.

Extended Test: [V] Sampling..

These will be averaged and the result displayed on the top line of the LCD display. Each incoming pulse will be analyzed and the result displayed on the bottom line of the display.

Av 5.0V 60BPM [V] 5.1V 62BPM

If the measured pulse differs from the average by more than 10% the Information will be sent to the printer. The printer will also print the number of pulses (up to 999,999) since the completion of the averaging of the first 10 pulses.

The purpose of this test is to report missing or incorrect pulses over an extended period of time without the necessity for the operator to watch the Pacemaker Analyzer continuously.

Press [>>] to terminate the test.

3.16 Sample Results from Supplementary Tests

```
          * PACEMAKER ANALYZER *    V2.9

Serial No    : AX103H
Model No     : EXAMPLE
Manufacturer : PM INC.
Location     : CARDIAC DEPT.
Hospital No  : CD2043
Technician   : W.H.SMITH.
Date         : 17 / JAN / 2003
Comment      OVERNIGHT TROUBLE REPORTED
Comment      ------------------------
Comment      ------------------------


INTERFERENCE SIGNAL
     60Hz      10mV

INTERFERENCE SIGNAL
     60Hz       4mV
   +SQU        2mV

T-SENSITIVITY
     4.8mV    [  70BPM     100mS    +SSQ]

S-SENSITIVITY
     1.2mV    [  70BPM      15mS    -SSQ]

PULSED REFRACTORY PERIOD
    220mS

SENSED REFRACTORY PERIOD
    290mS


EXTENDED TEST
[V]Av      5.0V      60BPM
faults:-
(1st column is beat number)
000036      5.1V      52BPM
000037      5.0V      52BPM
000038      5.0V      52BPM
000062      5.5V      59BPM
000063      5.6V      59BPM
000064      5.6V      59BPM
000065      5.7V      59BPM
000068      3.8V      59BPM

Total no. of beats - 000107
```

3.17 Operating with a Computer

If a computer is connected to the serial port and configured to receive data in the correct protocol (9600, N, 8, 1) then every time output appears on the printer, it will also be sent to the computer. This facility can be used to collect data directly into a computer file for 'paperless' data collection.

Interactive Mode, in which all information appearing on the LCD panel is returned to the computer, so that full control including some automatic testing is possible from a computer.

Commands to start tests.

%V	Ventricular test
%A	Atrial test
%T	Transthoracic test
%R	R-wave sensitivity
%S	S-wave sensitivity
%PRP	Pulsed refractory period
%SRP	Sensed refractory period
%A-V	Atrio-ventricular interval
%INT	Interference test
%EXT	Extended test

Commands to control tests in progress.

Pulse type	Y
Pulse width	W
Advance	>
Print	P
Rate up	G
Rate down	B
Amplitude up	H
Amplitude down	N
Ventricular	V
Atrial	A
Transthoracic	T
Yes	N
No	H
INH	B
TAK	G
R	N
T	H

If a test is entered manually (i.e. via the panel switches on the front of the Pacemaker Analyzer), it must be completed manually. Similarly, if a test is entered under computer control, the Pacemaker Analyzer panel switches will have no effect until the test is completed under computer control. Once the display returns to 'SELECT FUNCTION', any mode may be used to proceed.

4. TROUBLESHOOTING, SERVICE & CALIBRATION

4.1 Operating Precautions

The Pacemaker Analyzer is a complex electronic instrument which should not be subjected to extremes of temperature or humidity. If transferred from a very cold environment to a warm one, it may need a period to allow any condensation on the components to evaporate.

Use only with 1.5 volt AA cells (preferably alkaline type) and do not leave switched on unnecessarily when batteries are in use. Remove batteries for very long periods of storage. Use with an external power supply +6-9v (US version), according to connection diagram on rear of instrument.

Never use with pacemaker connected to a patient.

The load presented to the pacemaker is 500 ohms for invasive types and 50 ohms for transthoracic types. These values have been chosen to match most pacemakers in use. If the test load specified by the manufacturer is different from these values, then a scaling factor may have to be applied.

4.2 Cleaning

Clean the unit with a damp cloth with a small amount of detergent applied. Do not allow moisture to enter the instrument.

4.3 Service, Checking, Calibration

The calibration of the unit depends on the settings of internal potentiometers during manufacture or service by qualified personnel. If the unit has been opened since calibration, the settings of the potentiometers is unknown and the manufacturer/service organisation calibration is no longer valid.

The unit should be returned to the supplier periodically (e.g. yearly) for verification of calibration. Users are recommended to keep records of results from selected pacemakers (e.g. 1 invasive and 1 transthoracic type) for comparison with future test records. A change in results would suggest a need to have the calibration verified.

Some basic checks of performance and calibration can be undertaken without opening the instrument:

1. Assume the bottom row of buttons are [A] [B] [C] [D] from left to right. Switch on pressing [A]. The display will show the Program Version Number (e.g. 2.9). Ignore the other characters on the display.

2. Switch on pressing [B]. In this mode, pressing each button causes a number to appear on the display, and the internal loudspeaker to sound. Check that each button is working correctly. The numbers are as follows:

[134]	[166]		
[156]	[204]	[140]	[172]
[154]	[202]	[138]	[170]
[30]	[78]	[14]	[46]

3. Switch on pressing [C]. Connect d.c. voltmeter to input V. Note reading is +25mV +/-0.5mV. Press 'Tr.' button and note voltage is -25mV +/-0.5mV.

4. Switch on pressing [D]. Display now shows:

```
25mV +SQU
N1  N2  N3  N4
```

Where:
N1 = V input (Voltage = N/80)
N2 = A input (" ")
N3 = Tr input (" ")
N4 = Power supply voltage (N/102.5)

Check that N4 = 550-650 on batteries, and higher on external power input (if this is greater than 6V).

Connect a 10.0V d.c. source to input V and note that N1 is 800 +/-17.
Connect a 10.0V d.c. source to input A and note that N2 is 800 +/-17.

> **Warning** the following test must be completed in less than 10 seconds to ensure that internal components do not overheat.

Connect a 10.0V d.c. source to input Tr and note that N3 is 800 +/-17.

5. Switch on pressing [D]. Connect Oscilloscope to V input (suggested settings X=10mS/div, Y=10mV/div, Trig. dc, norm, +).
Check that waveform is approximately 15mS, 3Hz, 25mV. Use 'Tr.' button to verify the presence of all seven waveforms (+SQU, -SQU, +TRI, -TRI, +SSQ, -SSQ, ISO). Use amplitude buttons to check the reduction in amplitude agrees with the LCD display.

6. Switch on normally, and then select interference test 'INT' with no R-wave. Increase the amplitude to 25mV (peak to peak) using the Amplitude buttons. With oscilloscope connected to input V check the frequency and amplitude of the signal.

   Re-enter Interference test and choose the R-wave option. Accept the +SQUare wave, increase the amplitude to 25mV and then check the R=wave and Interference generated agree with the LCD display.

7. Connect to printer and check that header can be printed (press [Print] and [>>] together.

8. Connect to computer running a MODEM or COMMS program set to 9600, N, 8, 1 and check that header is received at same time as printing, and that basic commands work. For example try sending #V to initiate the Ventricular Pulse measurement test, and the sending > to return to manual operation.

4.4 Troubleshooting

At present, troubleshooting should be undertaken by the supplier. Difficulties experienced should be documented in full when returning the unit so that a proper appraisal of the problem can be undertaken.

Basic issues should be checked first such as the power supply (state of batteries). It should also be noted that absence of characters on the display may be due to incorrect adjustment of the LCD contrast display (see rear overlay for position).

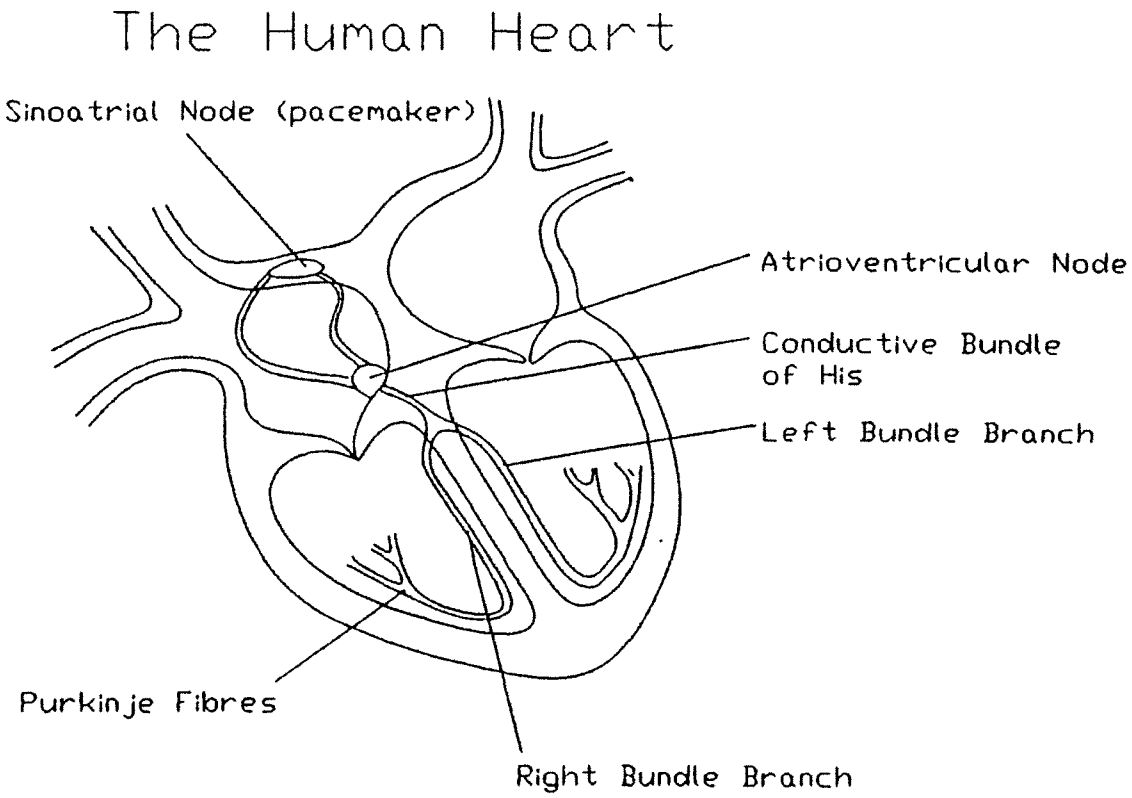
Pulse amplitude figures are subject to different definitions (peak/average/rms etc.), and different types of Pacemaker will produce difference pulse waveforms, which may suffer further variations in differing load condition. The pacemaker pulse amplitudes measured by the Pacemaker Analyzer are measured at 0.1mS after the beginning of the pulse for Invasive types, and after 2mS for Non-invasive types. These values have been chosen to represent the initial pulse amplitude with minimal effect from 'sag' or 'ringing' of the pulse which occurs with some pacemakers under simulated load conditions.

5. APPENDIX 1 External Pacemakers application and description

5.1 Cardiac Pacemakers

Normal operation of the heart and the Origin of the Electrocardiogram

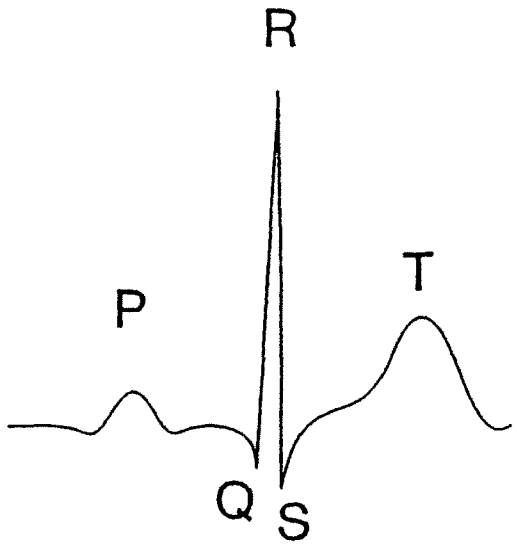
Cardiac Pacemakers replace or supplement the physiologic electrical system which normally initiates and controls cardiac contraction. If the natural pacemaker of the heart fails to act, or if the natural conduction system within the heart does not operate properly, an external stimulus at appropriate times can restore proper cardiac function.



The natural pacemaker of the heart is the Sinoatrial (SA) Node which depolarizes periodically (60-100 times per minute in the resting heart) producing a small electrical pulse. The rate is controlled by the demands of the body for blood output from the heart. The atria, filled by blood returning from the body (Right Atrium) and lungs (Left Atrium) contract in response to the sinoatrial pacing pulse, thus emptying blood into the ventricles.

The atrial contraction causes the P wave on the surface ECG due to the depolarizing of the muscle. The Atrioventricular (AV) Node then conducts the signal slowly to the HIS bundle, providing a delay to allow completion of atrial emptying into the ventricles. The signal is then conducted via the HIS bundle and the distribution of the Purkinje fibres to the ventricular myocardium (muscle). This produces contraction of the ventricles and ejection of blood into the arteries. The depolarizing of the

ventricular muscle causes the large QRS wave group (R-wave) on the surface ECG. The electrical recovery of the ventricles causes the T-wave. Thus the SA node provides the pacing rate, and the conducting fibres (AV node, HIS bundle and Purkinje fibres) provide the proper timing sequences.



5.2 Components of the Normal Surface Electrocardiogram

5.3 Dysrhythmia

Disturbance in either impulse generation or conduction (i.e. block) can change the heart performance which an electronic cardiac pacemaker can rectify, either totally or partially. Those disorders which can clearly benefit from pacemaker therapy include sinus arrest, sinus block, symptomatic sinus bradycardia, third degree AV block, symptomatic Mobitz Type II block, and bradytachy syndrome. Also some atrial and ventricular ectopic rhythms which originate elsewhere than in the SA and AV nodes, and tachycardias can often be managed using pacemakers. Bradycardia is slow heart beat, Tachycardia is rapid heart beat and Ectopic Rhythms are where extra beats occur over and above the basic rhythm.

5.4 Types of Pacemaker

Pacemakers may be fully implantable or external. The Pacemaker Analyzer is intended only for external types although many implantable types could be tested using the Pacemaker Analyzer outside the body. External pacemakers fall into two main types:

Invasive Pacemakers which are connected directly to the heart by leads passing through the skin, often passed along a vein. Since these devices have intracardiac connections, electrical safety requirements are much higher than for non-invasive types.

Non-invasive Pacemakers (Transthoracic) which apply pulses across or along the axis of the heart from large skin electrodes and sense the activity of the heart via normal ECG electrodes. Although generally less effective and less versatile than invasive or

implantable types, non-invasive pacers allow early institution of therapy, even outside the hospital.

5.5 Classification of Pacemakers

One method of classification of pacemakers which has been used is a 3 letter code as follows. This classification helps to illustrate the combinations which are possible.

Character 1 identifies the chamber to be paced:

A - Atrium
V - Ventricle
D - Dual (i.e. both)

Character 2 identifies the chamber sensed:

A - Atrium
V - Ventricle
D - Dual (i.e. both)
O - Character not pertinent

Character 3 identifies the mode of response:

I - Inhibited or blocked output in response to sensed signal
T - Triggered or Synchronized output
O - Character not pertinent

e.g.1 VOO is for ventricular simulation which does not sense heart activity and does not modify output in response to sensed activity.

e.g.2 VAT is for ventricular stimulation only which is triggered by sensed atrial signals.